

In the Claims:

The following is a complete listing of the claims, intended to replace any claims previously set forth in this matter. Please amend the claims as shown.

Claims 1-32 are CANCELLED.

33. (Currently Amended) A method for creating ~~and using~~ data associated with a product or device, wherein the method comprises the steps of:

accessing at least one adverse event data source ~~that stores~~ comprising previously gathered adverse event data associated with a product or device;

analyzing the adverse event data to identify new essential adverse events associated with the product or device;

creating at least one essential adverse event information database, wherein the creating step comprises analyzing data from the at least one adverse event data source to identify at least one new useful characteristic or use for the product or device responsive to identification of at least one new essential adverse event associated with the product or device, wherein the creating step further comprises storing essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic; ~~and~~

~~commercializing essential adverse event information stored at the essential adverse event information database.~~

34. (Originally filed) The method of claim 33, wherein accessing further comprises accessing the at least one adverse event data source comprising raw data from a plurality of different adverse events.

35. (Originally filed) The method of claim 33, wherein accessing further comprises accessing data from the at least one adverse event data source comprising adverse event information regarding exposure to or use of the product or device.

36. (Originally filed) The method of claim 35, wherein accessing further comprises accessing the at least one adverse event data source further comprising information regarding adverse events selected from at least two categories selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries.

37. (Originally filed) The method of claim 33, further accessing at least one data source comprising information relating to patents and patent applications.

38. (Originally filed) The method of claim 33, further accessing at least one data source comprising information relating to raw commercial or sales data.

39. (Currently Amended) The method of claim 33, ~~further comprising providing wherein~~ the at least one adverse event data source ~~comprising~~ comprises adverse event data gathered from at least 5000 subjects.

40. (Currently Amended) The method of claim 39, ~~further comprising providing wherein~~ the at least one adverse event data source ~~comprising~~ comprises information regarding amount of use of the product or device or duration of exposure to the product or device by each subject.

41. (Currently Amended) The method of claim 39, ~~further comprising providing wherein~~ the at least one adverse event data source ~~comprising~~ comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

Claims 42-45 are CANCELLED.

46. (Originally filed) The method of claim 33, further identifying the at least one new use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

47. (Originally filed) The method of claim 33, wherein the product or device is commercially available, and further identifying the new use as comprising restricting exposure of the product or device to one of the high risk associated groups selected from the group consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product or device with one of the group selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer; or exposure to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or exposure to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

48. (Originally filed) The method of claim 33, wherein the essential adverse event data is proprietary.
49. (Originally filed) A proprietary product or device created using the method of claim 33.
50. (Originally filed) The product of claim 33, wherein the product is medical.
51. (Originally filed) The product of claim 49, wherein the product is medical.
52. (Originally filed) The product of claim 50, wherein the medical product is a generic drug.
53. (Originally filed) The product of claim 51, wherein the medical product is a generic drug.
54. (Originally filed) The product of claim 33, wherein the product is non-medical.
55. (Originally filed) The product of claim 49, wherein the product is non-medical.
56. (Originally filed) The device of claim 33, wherein the device is medical.
57. (Originally filed) The device of claim 49, wherein the device is medical.
58. (Originally filed) The device of claim 33, wherein the device is non-medical.
59. (Originally filed) The device of claim 49, wherein the device is non-medical.
60. (Originally filed) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is created in accordance with claim 33.
61. (Originally filed) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is created in accordance with claim 46.
62. (Originally filed) The method comprising using the proprietary kit of claim 60 in accordance with a proprietary new characteristic of, or use for, a product or device.
63. (Originally filed) The method comprising using the proprietary kit of claim 61 in accordance with a proprietary new characteristic of, or use for, a product or device.

Claims 64-200 are CANCELLED.

201 (NEW) A method for using data associated with at least one database, wherein essential adverse event information is stored, and wherein the data therein is derived from an analysis of data from at least one adverse event data source of previously gathered data, and identifies at

least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic, said method comprising commercializing new essential adverse event information stored therein.

202. (New) The method of claim 201, wherein the at least one adverse event data source comprises adverse event data gathered from at least 5000 subjects.

203. (New) The method of claim 201, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

204. (New) The method of claim 201, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

205. (New) The method of claim 201, wherein commercializing further comprises selling, leasing or licensing the newly identified product information.

206. (New) The method of claim 201, wherein commercializing further comprises protecting the intellectual property interest in the newly identified product information.

207. (New) The method of claim 201, wherein commercializing further comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product or device.

208. (New) The method of claim 201, further comprising determining the value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event.

209. (New) The method of claim 201, wherein the at least one adverse event data source comprises the at least one new use of the product or device is a restricted use in at least one

population subgroup, when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

210. (New) The method of claim 201, wherein the product or device is commercially available, and the new use is further identified as comprising restricting exposure of the product or device to one of the high risk associated groups selected from the group consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product or device with one of the group selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer; or exposure to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or exposure to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

211. (New) The method of claim 201, wherein the essential adverse event data is proprietary.

212. (New) The product of claim 201, wherein the product is medical.

213. (New) The product of claim 210, wherein the product is medical.

215. (New) The product of claim 212, wherein the medical product is a generic drug.

216. (New) The product of claim 201, wherein the product is non-medical.

217. (New) The product of claim 210, wherein the product is non-medical.

218. (New) The device of claim 210, wherein the device is medical.

219. (New) The device of claim 210, wherein the device is medical.

220. (New) The device of claim 201, wherein the device is non-medical.

221. (New) The device of claim 210, wherein the device is non-medical.

222. (New) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is used in accordance with claim 201.

223. (New) A proprietary kit containing a product or device, and labeling notifying a user of at least one new essential adverse event for the product or device, wherein the kit is created in accordance with claim 209.

224. (New) The method comprising using the proprietary kit of claim 222 in accordance with a proprietary new characteristic of, or use for, a product or device.

225. (New) The method comprising using the proprietary kit of claim 223 in accordance with a proprietary new characteristic of, or use for, a product or device.

226. (New) A proprietary new use for a commercially available product or device, wherein the new use is in accordance with the method of claim 201.

227. (New) The proprietary new use for a commercially available product or device according to claim 226, wherein the new use is protected as an intellectual property.

228. (New) The proprietary new use for a commercially available product or device according to claim 226, wherein the new use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

229. (New) The proprietary new use of the product or device according to claim 228, wherein at least one new adverse event comprises a drug interaction.

230. (New) The proprietary new use of the product or device according to claim 228, wherein at least one new adverse event is not based on a chronic immune mediated disorder.

231. (New) The method in accordance with claim 201, further comprising establishing a new safety data sheet for a commercially available product or device, wherein the safety data sheet identifies at least one new essential adverse event for the at least one product or device.

232. (New) The method in accordance with claim 201, further comprising establishing a new safety data sheet, which lacks at least one proprietary non-essential adverse event for the at least one product or device.

233. (New) The safety data sheet produced in accordance with claim 231.

234. (New) The safety data sheet produced in accordance with claim 232.

235. (New) The method in accordance with claim 201, further comprising using the essential adverse data in a novel manner to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated with the product or device, or any combination thereof.

236. (New) The method in accordance with claim 210, further comprising using the essential adverse data in a novel manner to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated with the product or device, or any combination thereof.

237. (New) The method in accordance with claim 232, further comprising using the essential adverse data in a novel manner to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated with the product or device, or any combination thereof.

238. (New) The method in accordance with claim 201, further comprising using the essential adverse data in a novel manner to develop at least one essential proprietary new method of screening a product or device for safety.

239. (New) The method in accordance with claim 231, further comprising using the new safety data sheet to develop at least one essential proprietary new method of screening a product or device for safety.

240. (New) The method in accordance with claim 232, further comprising using the new safety data sheet to develop at least one essential proprietary new method of screening a product or device for safety.

241. (New) The method of claim 201, wherein commercialization comprises facilitating documentation of inventorship.

242. (New) The method of claim 241, further comprising documenting date of inventorship.

243. (New) The method of claim 241, wherein the product or device is commercially available and further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

244. (New) The method of claim 208, wherein the product or device is commercially available and further comprising identifying the new use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

245. (New) The product or device of claim 210, wherein the product or device is commercially available and wherein the new use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

246. (New) The method of using the proprietary kit of claim 222, comprising providing a proprietary new characteristic of, or use for the product of device, wherein the product or device is commercially available, and wherein the new use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

247. (New) The method of claim 33, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

248. (New) The method of claim 33, wherein at least one data source comprises information relating to patents and patent applications.

249. (New) The method of claim 33, wherein at least one data source comprises information relating to raw commercial or sales data.